K110092

APR - 8 2011

Section III - 510(k) Summary

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7602 - Phone
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Wendy Garman - Contact Person

Date Summary Prepared: April 2011

Device Name:

- Trade Name – *Take 1 Advanced Rigid Tray*
- Common Name – Dental Impression Material
- Classification Name – Impression Material, per 21 CFR § 872.3660

Devices for Which Substantial Equivalence is Claimed:

- Kerr Corporation, *Take 1 Advanced Rigid Tray, K092176*

Device Description:

The device is an addition-cure vinyl polysiloxane dental impression material that is used for all crowns and bridges, edentulous, orthodontic and implant impression techniques. *Take 1 Advanced Rigid Tray* is a two-part, base/catalyst – paste/paste system. The product is available in a heavy body viscosity, offered in cartridge 1:1 delivery and Volume 5:1 delivery, and in 3 setting speeds: regular set, fast set and super fast set.

Intended Use of the Device:

Take 1 Advanced Rigid Tray is an addition-cure vinyl polysiloxane dental impression material that is used for all crown and bridge, edentulous, orthodontic and implant impression techniques.

Summary of Technological Characteristics:

There has been no change made to design, composition, or intended use of *Take 1 Advanced Rigid Tray* as compared to its predicate. Additionally, *Take 1 Advanced Rigid Tray* has the same technological characteristics as its predicate. The only change being proposed is adding two new warnings to the Directions For Use. The new warnings state that *Take 1 Advanced Rigid Tray* is not recommended for use with impression trays spanning a full arch, and *Take 1 Advanced Rigid Tray* is not recommended for use in clinical situations where the opposing arch is a fixed partial denture.

Non-Clinical Test Data:

This 510(k) submission also includes data from bench testing used to evaluate the performance characteristics of *Take 1 Advanced Rigid Tray* compared to the predicate device, *Take 1 Advanced Rigid Tray, K092176*. The characteristics evaluated included, but were not limited to Working Time, Setting Time, Compressive Strength, Diametral Strength, Flexural Strength and Shore D Hardness.

A biocompatibility study (toxicity) has been completed according to ISO 10993, which demonstrates that *Take 1 Advanced Rigid Tray* is safe for its intended use.

Clinical Testing:

Clinical testing has not been conducted on this product.

Conclusion:

Based upon the biocompatibility test and the bench testing, the clinical performance of *Take 1 Advanced Rigid Tray* is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Kerr Corporation
C/O Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialties
1717 West Collins Avenue
Orange, California 92867

APR - 8 2011

Re: K110092
Trade/Device Name: Take 1 Advanced Rigid Tray
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: January 10, 2011
Received: January 12, 2011

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section I – Indications for Use

510(k) Labeling Change Being Effected
Sybron Dental Specialties, Inc.

Indications for Use

510(k) Number (if known): K110092

Device Name: *Take 1 Advanced Rigid Tray*

Indications For Use:

Take 1 Advanced Rigid Tray is an addition-cure vinyl polysiloxane dental impression material that is used for all crown and bridge, edentulous, orthodontic and implant impression techniques.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K110092